

K112998

MAR 15 2012

3 510(k) Summary**510(K) SUMMARY FOR AutoPulse® Resuscitation System Model 100****Submitter's Name, Address, Telephone Number, and Contact Person**

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Name of Device

AutoPulse® Resuscitation System Model 100

Common or Usual Name

Automatic Mechanical Chest Compressor

Classification Name

21 CFR 870.5200 External cardiac compressor

Device Class

Class III

Predicate Devices

Device Name	510(k) #	Decision Date	Decision
AutoPulse Resuscitation System Model 100	K072527	03/19/2008	Substantially equivalent (SE)
	K063602	12/21/2006	Substantially equivalent (SE)
	K040453	03/11/2004	Substantially equivalent (SE)
	K032852	11/12/2003	Substantially equivalent (SE)
	K022345	08/15/2002	Substantially equivalent (SE)
	K011046	10/25/2001	Substantially equivalent (SE)

Indications for Use

The AutoPulse Resuscitation System Model 100 is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by lack of spontaneous breathing and pulse.

The Indications for Use are unchanged.

Device Description

The AutoPulse Resuscitation System Model 100 is an automated, portable, battery powered device that compresses the chest of an adult human as an adjunct to manual CPR. A brief description of the device is provided below.

The AutoPulse System consists of 4 primary components, a reusable Platform, a single use chest compression assembly (LifeBand), a rechargeable battery, and a battery charger. The AutoPulse Platform contains the mechanical drive mechanism, control system, software and electronics necessary to generate and control the force required to perform mechanical chest compressions. User controls and indicators are contained in the User Control Panel. The AutoPulse Platform and LifeBand are unchanged. A new battery and battery charger are the subject devices of this 510(k).

Principles of Operation

The principle of operation remains unchanged. The AutoPulse Resuscitation System Model 100 is an electrically powered external cardiac compressor that compresses the chest in the region of the heart per AHA recommended protocol to provide blood flow during cardiac arrest. This principle of operation of the modified AutoPulse System that is the subject device of this 510(k) is identical to the principal of operation of the currently marketed AutoPulse System.

Summary of Testing

The changes included in this 510(k) application include the introduction of new Li-Ion battery and a multi-chemistry charger, capable of charging the current NiMH battery and the new Li-Ion battery. The charger has the built-in functional testing features to automate battery testing and battery maintenance tasks. There were no changes made to the AutoPulse Model 100 hardware, software or the operating specifications. There were no changes to the LifeBand.

The changes were extensively tested to verify the safety and efficacy of the entire system. First, the system level compatibility was verified to ensure that the AutoPulse powered with the new Li-Ion battery meets the operating parameters in a safe and intended manner. The data showed that the new battery chemistry did not alter functioning of the AutoPulse in any way and that it operates identically to the NiMH Battery powered AutoPulse.

Testing also included verification of the compatibility between the new multi-chemistry charger and the current NiMH battery. The bench testing showed that the new charger was capable of safely and consistently charging the NiMH battery, testing the battery and to

correctly identify when the end of life has been reached. The new charger also successfully demonstrated its ability to charge, test, maintain and identify the end of life conditions per the Li-Ion battery specifications.

Extensive bench testing was conducted to verify ability of the Li-Ion battery to meet the performance safety specifications. The testing included charging/discharging characteristics of the battery, ability to power the AutoPulse for the specified runtime throughout the specified life of the battery, environmental testing, electrical safety and electromagnetic compatibility. A partial list of international standards applied in the testing includes but is not limited to: applicable parts of IEC 60601-1, IEC 60601-1-2, IEC 60068 series, IEC 61000, CISPR11, IEC 62133 etc.

Summary of the Basis for Finding of Substantial Equivalence

The proposed AutoPulse Resuscitation System Model 100 is identical to the previously cleared device. The proposed system:

- has the same intended use;
- uses the same operating principles;
- incorporates the same device design;
- has the same performance specifications;
- incorporates a new battery and battery charger which have the same operating principles as those of the predicate device;
- incorporates the same hardware and software functions.

Rational for Equivalence

There are two (2) minor technological changes to the currently marketed AutoPulse System that are proposed in this 510(k):

- i) a new rechargeable battery pack using Lithium Ion (Li-Ion) chemistry battery cells; and
- ii) a new battery charger (the AutoPulse Multi-Chemistry Charger) capable of charging both the currently marketed nickel metal hydride (NiMH) battery and the new Li-Ion Battery. The addition of the new battery to the AutoPulse System and charger will not alter the function or performance of the AutoPulse System.

There are no changes proposed to the Indications for Use, the AutoPulse Platform, and the single use, non-sterile LifeBand. The instructions for use are updated with directions for using the new battery and battery charger. Bench Testing results were sufficient to assure that the design changes raised no new issues of Safety and Effectiveness. The subject AutoPulse Resuscitation System Model 100 is thus substantially equivalent to its predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MAR 15 2012

Zoll Circulation
c/o Mr. Sam Nanavati
Vice President, Quality & Regulatory Affairs
650 Almanor Avenue
Sunnyvale, CA 94085

Re: K112998
AutoPulse Resuscitation System Model 100
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III
Product Code: DRM
Dated: February 27, 2012
Received: February 28, 2012

Dear Mr. Nanavati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

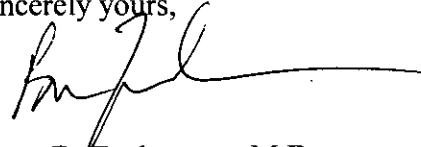
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112998

Device Name: AutoPulse Resuscitation System Model 100

Indications For Use:

The AutoPulse Resuscitation System Model 100 is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by lack of spontaneous breathing and pulse.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112998